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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/836,347	04/18/2001	William A. Koehring	N1239-008	8757
32905	7590 04/30/2003			
JONDLE & ASSOCIATES P.C. 9085 EAST MINERAL CIRCLE SUITE 200			EXAMINER	
			KRUSE, DAVID H	
CENTENNIA	L, CO 80112		ART UNIT	PAPER NUMBER
			1638	
			DATE MAILED: 04/30/2003	14

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		09/836,347	KOEHRING ET AL.
		Examiner	Art Unit
		David H Kruse	1638
Period fo	The MAILING DATE of this communication app		
A SH THE I - Exter after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply specified above is less than thirty (30) days, a reply of period for reply is specified above, the maximum statutory period we reto reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be to within the statutory minimum of thirty (30) day ill apply and will expire SIX (6) MONTHS from Cause the application to become ARANDON.	imely filed  ays will be considered timely.  The mailing date of this communication.
1)⊠	Responsive to communication(s) filed on 12 F	ebruary 2003 .	
2a)⊠	This action is <b>FINAL</b> . 2b) Thi	s action is non-final.	
3)□ Dispositi	Since this application is in condition for allowa closed in accordance with the practice under <i>t</i> on of Claims	nce except for formal matters, p Ex parte Quayle, 1935 C.D. 11,	prosecution as to the merits is 453 O.G. 213.
4)⊠	Claim(s) 1-11 and 33-49 is/are pending in the	application.	
•	4a) Of the above claim(s) is/are withdraw	n from consideration.	
5)⊠	Claim(s) <u>1-9,11 and 36-47</u> is/are allowed.		
6)⊠	Claim(s) 10, 33-35, 48 and 49 is/are rejected.		
7)	Claim(s) is/are objected to.		•
8)[	Claim(s) are subject to restriction and/or	election requirement.	•
Application	on Papers		
	The specification is objected to by the Examiner		
10)□ Т	he drawing(s) filed on is/are: a)□ accept	ted or b) $\square$ objected to by the Exa	miner.
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. S	See 37 CFR 1.85(a).
11)∐ T		is: a) ☐ approved b) ☐ disappro	oved by the Examiner.
	If approved, corrected drawings are required in repl		
	he oath or declaration is objected to by the Exa	miner.	
	nder 35 U.S.C. §§ 119 and 120		•
	Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a	a)-(d) or (f).
a)[	☐ All b)☐ Some * c)☐ None of:	•	
	<ol> <li>Certified copies of the priority documents</li> </ol>	have been received.	
2	2. Certified copies of the priority documents	have been received in Applicati	on No
	3.☐ Copies of the certified copies of the priorit application from the International Bure se the attached detailed Office action for a list o	eau (PCT Rule 17 2(a))	
	knowledgment is made of a claim for domestic		
a) 15)∭ Ad	The translation of the foreign language provocknowledgment is made of a claim for domestic	isional application has been rec	eived.
Attachment(	of References Cited (PTO-892)		
!)	of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	4) Interview Summary 5) Notice of Informal F 6) Other:	(PTO-413) Paper No(s) Patent Application (PTO-152)
Patent and Trac O-326 (Rev.	· · ·	on Summary	Part of Paper No. 14

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## STATUS OF THE APPLICATION

This Office action is in response to the Amendment and Remarks filed 12
 February 2003.

- 2. Claims 12-32 have been cancelled as requested and new claims 34-49 have been entered.
- 3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendment and/or Remarks filed 12 February 2003.
- 4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## Claim Rejections - 35 USC § 112

5. Claim 10 remains rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the designation "RBO1" does not denote an art recognized designation of a corn plant and hence does not state the metes and bounds of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2002. Applicant's arguments filed 12 February 2003 do not specifically address this rejection, only states that variety RB01 will be deposited upon allowance of any claims (page 5, 4<sup>th</sup> paragraph of the Remarks). In a addition, the phrase "produced by a tissue culture processing obtaining" does not make sense and does not state the metes and bounds of the claimed invention. The following claim language is suggested:

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— A corn plant with all of the physiological and morphological characteristics of corn inbred RBO1, representative seed of said inbred RBO1 having been deposited under ATCC Accession No. \_\_\_\_, wherein said corn plant is produced by propagating said corn plant from the corn plant of claim 5 by a tissue culture process. — \_\_\_\_

6. Claim 33 remains rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2002. Applicant's arguments filed 12 February 2003 have been fully considered but are not found to be persuasive.

Applicant's response only addresses the issue of proper Markush language in recitation of a list of species, and does not address the issue of use of the phrase "single gene conversion" that is deemed repugnant to the usual meaning in the art as outlined in the previous Office action on page 6. This rejection is maintained.

7. Claim 33 remains rejected and claims 34 and 35 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2002. Applicant's arguments filed 12 February 2003 have been fully considered but are not found to be persuasive.

To the extent that claim 33 reads on a corn plant comprising a "single gene conversion" wherein said "single gene" is introduced by a backcrossing technique, it is

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unclear that Applicant could adequately describe such a plant because it is unclear that one of skill in the art could reproduce a RBO1 inbred corn plant that would have a single gene introduced by backcrossing from another, unidentified plant as broadly claimed.

Applicant does not specifically address the rejection as directed to claim 33 in the Remarks (see page 7 of the Remarks).

Applicant argues that at the time the application was filed, applicant was in possession of at least two hybrids as identified in Table 1 to 3 of the application (page 7 of the Remarks). This argument is not found to be persuasive as directed to claims 34 and 35 because the showing of possession of two hybrids does not adequately describe the claimed genus of hybrid corn seed. See *Lockwood v. American Airlines Inc.* (CA FC) 41 USPQ2d 1961, 1966 (3/4/1997). In addition, Applicant does not describe the genetic material of deposited line RBO1, hence Applicant has failed to adequately describe a hybrid corn seed wherein at least fifty percent of its genetic material originates form the pollen or ovule of the inbred corn line designated RBO1.

8. Claim 33 remains rejected and claims 34 and 35 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 13 August 2002. Applicant's arguments filed 12 February 2003 have been fully considered but are not found to be persuasive.

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Applicant's arguments as directed to the use of the phrase "single gene conversion" in other US Patents is irrelevant to the instant rejection because each application is examined upon its own merits (page 12 of the Remarks).

Applicant argues that a plant breeder shall readily use the corn line of the present invention for backcrossing, leading to an RBO1 corn plant further comprising a single gene conversion (page 12, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because the specification teaches that the breeder has no direct control at the cellular level and that two breeders will never develop the same line, or even very similar lines, having the same corn traits (page 2, paragraph 0008 of the specification). Therefore, it is unclear from the teachings of the instant specification how one of skill in the art could predictably produce the corn plant of claim 33 comprising a "single gene conversion" without undue trial and error experimentation. At claims 34 and 35, Applicant argues that for a plant breeder skilled in the art of corn breeding, the creation of an F1 hybrid is highly predictable (page 9, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because Applicant admits that the breeder can theoretically generate billions of different genetic combinations via crossing, and that the breeder has no direct control at the cellular level (page 2, paragraph 0008 of the specification). Applicant has only provided guidance for how to make and use two hybrid plants using inbred RBO1 as one of the parental lines. See In re Fisher, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

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In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

- 9. Claims 48 and 49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention because said claims appears to employ novel plants. Since the plants are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plants are not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plants and it is not apparent if the plants are readily available to the public.
- (a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed

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upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

- (b) If the deposit was <u>not</u> made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that
  - (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
  - (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
  - (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
  - (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
  - (v) the deposit will be replaced if it should ever become inviable.

In the paragraph spanning pages 12-13 of the Remarks, Applicant acknowledges the requirement for a deposit of biological material for inbreds RBO1, LH185 and LH287, but Applicant only indicates that deposits of RBO1 will be made with ATCC. Because a deposit of inbreds LH185 and LH287 are required to enable claims 48 and 49 said claims are not enabled. See *Ex parte Humphreys* 24 USPQ2d 1255, 1259

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(BdPatApp&Int, 1992) which teaches that the ability of others to obtain material from a third party prior to and after the filing date of an application does not establish that upon issuance of a patent on such application that such material will continue to be accessible to the public.

### Relevant Art

10. The Examiner herein cites the art relevant to claims 48 and 49 as Foley, US Patent 6,281,414, which claims inbred corn line LH287, and Miller, US Patent 5,416,261, which claims inbred corn line LH185. The cited prior art is relevant because Applicant has claimed a hybrid corn plant produced by crossing the exemplified RBO1 inbred corn line with either LH287 or LH185 corn lines. These references have been cited in the Information Disclosure Statement filed 15 October 2001.

#### Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- 12. Claims 1-9, 11 and 36-47 are allowed.
- Claims 10 and 33 remain rejected and new claims 48 and 49 are rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703)

306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m.

to 4:30 p.m.

13.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

> DAVID T. FOX PRIMARY EXAMINER

David H. Kruse, Ph.D. 29 April 2003